201 KAR 2:240. Special limited pharmacy permit - charitable.

RELATES TO: KRS 315.035
STATUTORY AUTHORITY: KRS 315.020, 315.030, 315.035, 315.191(1)(a)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations to prescribe the criteria for obtaining a pharmacy permit to dispense legend drugs and the procedures for the safe dispensing of legend drugs to citizens of the Commonwealth. This administrative regulation identifies the manner and procedure by which a charitable organization may obtain a pharmacy permit and dispense legend drugs in the Commonwealth.

Section 1. Definitions. (1) "Charitable organization" means an organization qualified as a charitable organization pursuant to Section 501(c)(3) of the Internal Revenue Code.
(2) "Legend drug sample" means an unopened package of a manufacturer's legend drug product that has been distributed to either a practitioner or the charitable pharmacy in accordance with the provisions of the Prescription Drug Marketing Act of 1987.
(3) "Qualified indigent patient" means a patient of the charitable pharmacy that has been screened and approved by the charitable organization as meeting the organization's mission of providing pharmaceutical care to those who are without sufficient funds to obtain needed legend drugs.
(4) "Special limited pharmacy permit" means a permit issued to a pharmacy that provides miscellaneous specialized pharmacy service and functions.

Section 2. (1) A charitable pharmacy:
(a) Shall comply with all pharmacy permit requirements except those specifically exempted by the board pursuant to paragraph (b) of this subsection; and
(b) May petition the board in writing to be exempted from those pharmacy permit requirements that do not pertain to the operation of that charitable pharmacy.
(2) The charitable pharmacy only shall dispense prescription legend drug samples or prescription legend drugs to qualified indigent patients of the pharmacy.
(3) The charitable pharmacy shall not charge any fee for the dispensing of prescription legend drug samples or prescription legend drugs to qualified indigent patients of the pharmacy.
(4) A charitable pharmacy may accept prescription legend drugs in their unbroken original packaging from pharmacies, wholesalers, or manufacturers, provided appropriate records of receipt and dispensing are maintained.
(5) A charitable pharmacy shall not:
(a) Accept controlled substances from pharmacies, wholesalers, or manufacturers; or
(b) Dispense controlled substances.
(6) A pharmacy that requests a special limited pharmacy permit - charitable shall submit to the board for prior approval, a plan describing the method by which the charitable pharmacy and the pharmacy will maintain a separate and distinct prescription drug stock. The failure of either pharmacy to follow the plan shall result in revocation of the special limited pharmacy permit – charitable and the pharmacy permit.

Section 3. License Fees; Renewals. An applicant shall submit:
(1) An initial or renewal application for a special limited pharmacy permit - charitable pharmacy on either the Application for Special Limited Pharmacy Permit - Charitable Pharmacy or the Application for Special Limited Pharmacy Permit - Charitable Pharmacy Renewal; and
(2) As appropriate, the:

(a) Initial application fee established by 201 KAR 2:250, Section 1(9); or

(b) Renewal fee established by 201 KAR 2:250, Section 1(10) and (11).

Section 4. Incorporation By Reference. (1) The following material is incorporated by reference:

(a) "Application for Special Limited Pharmacy Permit - Charitable Pharmacy", May 2019; and

(b) "Application for Special Limited Pharmacy Permit - Charitable Pharmacy Renewal", May 2019.

(2) This form may be obtained, inspected, or copied subject to applicable copyright law at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601, 8 a.m. to 4:30 p.m., Monday through Friday. (27 Ky.R. 254; 739; eff. 9-11-2000; 45 Ky.R. 3458; 46 Ky.R. 413; eff. 8-19-2019.)